K012097

JUL 12 2001

510(k) SUMMARY

In accordance with the provisions of the Safe Medical Device Act of 1990, UltraVisual Medical Systems is providing a summary of safety and effectiveness information regarding the Vortex™ software.

1.1 Company Identification

UltraVisual Medical Systems
131 W. Wilson Street
Suite 700
Madison WI 53703
Tel: 608 256 7775
Fax: 608 256 7779
Email: icouture@ultravisual.com

1.2 Official Correspondent

Gary J. Allsebrook
Regulatory Management Services
16303 Panoramic Way
San Leandro, CA, USA, 94578-1116
Tel: 510-276-2648
Fax: 510-276-3559
Email: regman1@home.com

1.3 Date of Submission

June 13, 2001

1.4 Device Name

Classification Name:	Image Processing System, 21 CFR §892.2050, ProCode LLZ
Common/Usual Name:	Teleradiology System
Proprietary Name:	Vortex™

1.5 Substantial Equivalence

The UltraVisual Vortex™ software is substantially equivalent to the Voxar Plug 'n View, K992654 and the AMICAS Web/Intranet Image Server, K970064).

1.6 Device Description and Intended Use

UltraVisual Vortex™ is an integrated client-serversoftware package, which may be marketed as software only, that is used in conjunction with standard PC hardware. UltraVisual Vortex™ is a PC-based, DICOM-compliant PACS device that is able to receive, transmit and display DICOM images over both local and wide area network. Images sent to the UltraVisual Vortex™server are converted into formats suitable for viewing in a web browser, and stored in a local cache (hard disk). The algorithms used by UltraVisual Vortex™to create JPEG and wavelet images follow known and accepted protocols.

Vortex™ can be used within a hospital, a managed care facility or an isolated imaging center. It can also be used for image distribution over the network for teleradiology/review purpose.

UltraVisual Vortex™ uses standard "off-the-shelf" PC hardware and communicates using the standard TCP/IP stack.

1.7 Software Development

Ultravisual certifies that the Vortex™ software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications and designs, coding and unit testing, validation testing and field maintenance.

1.8 Safety and Effectiveness

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and indications for use.

The hardware components specified (and/or optionally supplied) are all "off the shelf" computer components.

Validation and Effectiveness:

Extensive testing of the software package has been performed by programmers, by non-programmers, quality control staff, and by potential customers.

Substantial Equivalence:

The Ultravisual Vortex™ software is an integrated client-server software package used to receive DICOM images, convert them to an internal format, and to transfer those converted images to a viewing client.

Ultravisual Vortex™ has Indications for Use similar to other medical image devices such asAMICAS Web/Intranet Image Server (K970064) and Voxar Plug-n-View (K992654). Vortex™ also shares with these devices a Target Population that is competent healthcare professionals.

Like the AMICAS Web/Intranet Image Server (K970064) product, Vortex™ receives DICOM images on the server, converts them to wavelet format and displays them within a web enabled application at the client system.

Like the Voxar Plug 'n View (K992654) product, Vortex™ also provides tools for both 2D and 3D visualization of images, such as Volume Rendering, Multi Planar Reformatting (MPR) and Maximum Intensity Projection (MIP).

Any differences between the Ultravisual Vortex™ software and the equivalent devices have no significant influence on safety or effectiveness.

It is our conclusion that there is no software component in the UltraVisual Vortex™product or hardware component which would be used in conjunction with the UltraVisual Vortex™product that we know of whose failure or latent design flaw would be expected to result in death or injury to a patient. Thus the "Level of Concern" of the Ultravisual Vortex™ product is "minor".

1.9 Substantial Equivalence Chart

Product Name	UltraVisual Vortex™	AMICAS	Voxar
Windows O.S. - Client	Yes	Yes	Yes
Uses Standard. Monitor	Yes	Yes	Yes
Scales Image to Display.	Yes	Yes	Yes
Image Input	DICOM 3.0	DICOM 3.0	DICOM 3.0
Images stored on remote NT server	Yes	Yes	-
Network Protocol	TCP-IP	TCP-IP	TCP-IP
Compression	Wavelet/JPEG	Wavelet	-
Image Measurement	Yes	Yes	Yes
Cine tool	Yes	Yes	Yes
Comparison Mode	Yes	Yes	Yes
Flip / Rotate of Images	Yes	Yes	Yes
Patient & Study Browser	Yes	Yes	Yes
Volume Rendering	Volume rendering with interactive opacity/ transparency control, clipping volume of interest (VOI), zoom, pan and rotate	-	Same
Multi-Planar Reformatting (MPR)	MPR into any user-defined linear plane.	-	Same
Maximum Intensity Projection (MIP)	MIP with interactive window-level, clipping VOI, zoom, pan and rotate	-	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

UltraVisual Medical Systems
% Mr. Mark Job
TUV Product Service, Inc.
1775 Old Highway 8
NEW BRIGHTON MN 55112

Re: K012097
Vortex (TELERADIOLOGY SYSTEM)
Dated: July 2, 2001
Received: July 5, 2001
Regulatory Class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K012097

Device Name: Ultra Visual Medical Systems, *Vortex*™ Image Processing, Communication and Visualization Workstation

Indications For Use:

The system is designed to provide image storage, display, and workflow integration capabilities for healthcare enterprises. The image display architecture provides workgroup diagnostic viewing capabilities for radiologists as well as image reviewing functionality for referring physicians and other clinicians. In addition to traditional 2D image viewing functionality, the image display system provides advanced 3D features including volume rendering and multi-planar reconstruction designed to function in web-enabled viewers over both local and wide area networks.

Intended users of the image distribution system include radiologists, referring physicians, tertiary care physicians, medical technologists, and information technology professionals.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use____
(Per 21 CFR 901.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012097